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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
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09/778,154

02/05/2001

Seo Hong Yoo

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12/31/2002

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EXAMINER

KIM, VICKIE Y

ART UNIT

PAPER NUMBER

1614

DATE MAILED: 12/31/2002

Please find below and/or attached an Office communication concerning this application or proceeding.

# Office Action Summary

Application No.

09/778,154

Applicant(s)

YOO, SEO HONG

Examiner

Vickie Kim

Art Unit

1614

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --  
Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

## Status

- 1) ☐ Responsive to communication(s) filed on \_\_\_\_.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

## Disposition of Claims

- 4) ☒ Claim(s) 1-147 is/are pending in the application.
- 4a) Of the above claim(s) 1-137 is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 138-147 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_ are subject to restriction and/or election requirement.

## Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
- Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☐ The proposed drawing correction filed on \_\_\_\_ is: a) ☐ approved b) ☐ disapproved by the Examiner.
- If approved, corrected drawings are required in reply to this Office action.
- 12) ☐ The oath or declaration is objected to by the Examiner.

## Priority under 35 U.S.C. §§ 119 and 120

- 13) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some \* c) ☐ None of:
- ☐ Certified copies of the priority documents have been received.
  - ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_.
  - ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- \* See the attached detailed Office action for a list of the certified copies not received.
- 14) ☒ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).
- a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☒ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

## Attachment(s)

- 1) ☒ Notice of References Cited (PTO-892) 4) ☐ Interview Summary (PTO-413) Paper No(s). \_\_\_\_.
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948) 5) ☐ Notice of Informal Patent Application (PTO-152)
- 3) ☒ Information Disclosure Statement(s) (PTO-1449) Paper No(s) 10. 6) ☐ Other: \_\_\_\_.

## **DETAILED ACTION**

### ***Election acknowledged***

1. Applicant's election of Group VI: Claims 48-77, 81 and 138-147 and election of species, ursodeoxycholic acid for sub group I and a starch conversion product for sub group II, in Paper No. 9 are acknowledged. The elections of Group Vi and species(ursodeoxycholic acid and starch conversion product) is confirmed again thru telephonic conversation with Mr. Neil Sirota.
2. Regarding claims 88-96 and 129-137, the said claims are inadvertently omitted from previous restriction requirement. The claims 88-96 are drawn to a method comprising administration of an oral liquid form of bile acid composition having bile acid component, second materials and water as said in claim 138. The claims 129-137 are drawn to a method for achieving Cmax of about 0.3 to about 1.6 with a Tmax of less than about 3.5 hours using the said bile acid composition. As to the claims 88-96, due to it's generic feature that broadly covers the claimed subject matter of the inventions, groups I-V, a method of treating various diseases using the same bile acid composition, the claims 88-96 are now properly included in the groups I-IV and V as a commonly shared claims . The claims 129-137 are properly included in the Group IX.
3. Applicant's courteous remarks and the patience are appreciated. The examination will be performing based on the elected claims and elected species. Non-elected groups and species will be withdrawn from the consideration.

### ***Status of Application***

4. The claims 1-147 are pending.

5. Non-elected groups (claims 1-47, 78-80, 82-137) and non-elected species (claims 48-77 and 81) will be withdrawn from consideration.
6. The elected claims 138-147 are presented for the examination.

***Claim Objections***

6. Claims 143-147 are objected to under 37 CFR 1.75(c), as being of improper dependent form for failing to further limit the subject matter of a previous claim. Applicant is required to cancel the claim(s), or amend the claim(s) to place the claim(s) in proper dependent form, or rewrite the claim(s) in independent form. The claims are further limiting use of the bile acid composition rather than the structure of the bile composition. It is noted that the subject matter of the claim 138 is drawn to a clear aqueous solution of bile acid (composition).

***Claim Rejections - 35 USC § 112***

7. The following is a quotation of the second paragraph of 35 U.S.C. 112:  

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.
8. Claims 139, 142 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

The claims 139 and 142 recite the limitation "the dosage form or the oral liquid dosage form" in claim 138. There is insufficient antecedent basis for this limitation in the claim. The claims 139 and 142, therefore, should be considered to be the same as claim 138 (i.e. a clear aqueous solution).

***Claim Rejections - 35 USC § 102***

9. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

10. Claims 138-147 are rejected under 35 U.S.C. 102(b) as being anticipated by Nakazawa et al (JP62153220-abstract only). *CAPLUS abstract of JP*

JP'220 teaches an oral aqueous clear solution comprising bile acids(e.g. ursodeoxycholic acid) and dextrans(e.g. amyloextrin, D-glucose, water, etc. It further teaches that the said bile acid composition can be formulated and satisfied as internal medication without pH adjustment, see entire abstract(English translated JP abstract and CAPLUS(database) version).

All the critical elements required by the instant claims are taught by the reference and the all the claimed subject matter is anticipated.

Thus, the claims are properly included in this rejection.

### **Conclusion**

11. No claim is allowed.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Vickie Kim whose telephone number is 703-305-1675. The examiner can normally be reached on Tuesday-Friday. If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Marianne Seidel

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can be reached on 703-308-4725. The fax phone numbers for the organization where this application or proceeding is assigned are 703-746-3165 for regular communications and 703-746-3165 for After Final communications. Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is 703-308-1235.

**VICKIE KIM**  
**PATENT EXAMINER**

Vickie Kim,  
Patent examiner  
December 27, 2002  
Art unit 1614